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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,737	07/20/2001	Jonathan Gressel	01/22288	8906

7590

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

13

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/889,737	Applicant(s) GRESSEL, JONATHAN	
	Examiner David T. Fox	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 12-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The application should be reviewed for errors. Errors appear, for example, in claim 25, line 5, where a comma should be inserted between "growth" and "non".

Applicant's amendment of 19 May 2003 has overcome the indefiniteness rejections of the last Office action.

Claims 24-26 (newly added) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24-26, drawn to methods, fail to further limit the claims from which they depend, drawn to genetic constructs. Amendment of claims 24-26 to replace "method" in line 1 with --genetic construct-- would obviate this rejection.

Claims 16, 18, 24 and 26 (newly submitted) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite particular genes, namely an herbicide-resistant AHAS gene, an endo-beta-mannase gene, a sterol-C24-methyltransferase gene, and a 22- alpha-hydroxylase cytochrome P450 gene. However, there is no basis in the specification for any of these genes. Accordingly, these claims are drawn to NEW MATTER.

Art Unit: 1638

Claims 14-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 2-4 of the last Office action for claims 5-11.

Claims 14-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on pages 4-8 of the last Office action for claims 5-11.

Claims 19, 21, 23 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Klee et al (U.S. 5,512,466), as stated on page 8 of the last Office action for claims 5, 6 and 8.

Claims 19, 21, 23 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Yanofsky et al (U.S. 6,198,024 effectively filed June 1997), as stated on pages 8-9 of the last Office action for claims 5, 6 and 8.

Claims 19, 21, 23 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaller et al, as stated on page 9 of the last Office action for claims 5, 6 and 10.

Art Unit: 1638

Claims 19, 21, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/34088 (COLD SPRING HARBOR), as stated on page 10 of the last Office action for claims 5, 6 and 11.

Claims 19, 21, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al, as stated on pages 10-11 of the last Office action for claims 5, 6 and 11.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 22 (newly submitted) is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Klee et al, Schaller et al, COLD SPRING HARBOR, and Wang et al.

The claim is drawn to a genetic construct comprising an agronomic gene functionally linked to a second gene deleterious to a weed but benign to a crop species, wherein said genetic construct was obtained by a process comprising sequential transformation with a single component of the construct. Each of the cited references teach the claimed construct, albeit produced by a different method, as discussed above. However, the method of making the construct would not impart a unique property to the construct which would distinguish it from the prior art construct. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be

Art Unit: 1638

properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claims 14-18, 20, and 24 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest genetic constructs with an agronomic gene covalently linked to a second gene deleterious to weeds but not crop species, a genetic construct comprising an AHAS gene linked to the deleterious gene, or a method for mitigating transgene escape into weeds comprising introducing into a crop species a genetic construct comprising an agronomic gene linked to a second gene deleterious to weeds but benign to crop plants.

No claim is allowed.

Applicant's arguments filed 19 May 2003, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the written description rejection is improper, given the lack of a requirement that every claimed species be described, the knowledge in the art of genes suitable for use in the instant method, the guidelines in the specification for identifying such genes, the knowledge in the art of crop/weed combinations, and the obtention of such constructs by Al-Ahmad et al as discussed in the Gressel declaration and the draft publication appended thereto.

The Examiner maintains that the specification is completely silent with regard to the structure (i.e. sequence) of even a single gene which is agronomically desirable or which is benign to crops but deleterious to weeds. No names of even the particular enzymes encoded by agronomically desirable genes are provided. Although a few

Art Unit: 1638

examples of individual enzymes encoded by the deleterious genes are named, no other information is given regarding the isolation or characterization of the genes encoding them. Thus, absolutely no structural information is disclosed, wherein a disclosure of the structural features correlated with function (agronomic improvement or weed toxicity) is required to adequately describe a broad genus, per MPEP 2163.

Regarding the alleged knowledge in the art, the Examiner maintains that the instant specification must provide adequate written description, and that the availability of the putative genes prior to the instant invention is unclear.

Regarding the guidelines in the specification, the Examples are merely prophetic narratives which do not identify any particular gene or genetic sequence responsible for the claimed effects.

Regarding the knowledge in the art of particular crop/weed combinations, this knowledge does not remedy the lack of written description of even a single gene or transgene to be introduced into the crop or weed species.

Regarding Al-Ahmad et al, the authors utilize an AHAS gene and a *gai* gene, neither of which were even mentioned in the instant specification, and the availability of the *gai* gene prior to the instant invention is unclear. Furthermore, the *gai* gene introduced into tobacco was deleterious rather than benign to this cultivated crop, resulting in greatly decreased survival and sterility even when viable. Thus, the *gai* gene does not appear to be a member of the broadly claimed genus.

Applicant urges that the enablement rejection is improper, given the amendments to the claims, the lack of applicability of the references cited by the Examiner, the

Art Unit: 1638

guidance in the specification, the pioneering nature of the invention as also asserted in the Gressel declaration, and the demonstration of success by Al-Ahmad et al as discussed in the Gressel declaration and the draft publication appended thereto.

The Examiner maintains that the amendments to the claims to characterize weeds as "undesirable, uncultivated interbreeding species related to the cultivated crop plant" contradicts Applicant's arguments that Desplanque et al is inapplicable because the specification differentiates between cultivated weeds and "weed beets". Applicant's definition in the specification of "weed" as a plant of the same species as a cultivated crop, but said weedy plant merely occurring in an undesired location (i.e. "weed beets"), contradicts the newly claimed definition of "weed".

Regarding the remaining references, the Examiner maintains that the references demonstrate the unpredictability regarding the identification and expression of "deleterious" or "benign" traits in crops and weed species, whether or not these traits were introduced by transgenic methods or other means. In the absence of any demonstration of reduction to practice in the instant specification, such evidence outweighs mere assertions by Applicant.

Regarding the alleged guidance in the specification, the Examiner maintains that the specification recites the names of few actual enzymes encoded by putative genes, provides no evidence of the isolation of even a single gene or its introduction into weedy or crop species, and provides no evidence of success to rebut the Examiner's position.

Regarding the pioneering nature of the invention, the Examiner agrees. However, the claims are broadly drawn to any "commercially desirable" gene and any

Art Unit: 1638

deleterious gene (claims 14 and 19), any gene encoding any enzyme which somehow confers a laundry list of traits (claims 15, 17, 23 and 25), and a laundry list of unrelated genes for which no sequence information or other evidence of isolation is provided (claims 18 and 26). In contrast, the specification provides no guidance for even one of these genes or concepts, or its use to transform crop and weed plants and successfully obtain the claimed effects. Thus, the specification does not provide any degree of enablement, let alone a degree of enablement which is reasonably correlated with the claim scope. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970), which teaches that the allegedly pioneering nature of an invention does not obviate the need for "a reasonable correlation" between the scope of the claims and "the scope of enablement provided by the specification", wherein "the scope of enablement obviously varies conversely with the degree of unpredictability of the factors involved" in "cases involving unpredictable factors, such as most chemical reactions and physiological activities".

Regarding the Al-Ahmad et al publication, the Examiner notes that the instant specification is completely silent with regard to even the use of an AHAS gene or a *gai* gene, let alone their isolation or actual evaluation in transformed plants. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Furthermore, the availability of the *gai* gene in isolated form, for transgenic insertion, prior to the filing date of the instant application, is unclear. It is noted that Al-

Art Unit: 1638

Ahmad et al has not yet been published. See *In re Glass*, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification.

Finally, Al-Ahmad et al teach that the *gai* gene was deleterious rather than benign to the cultivated tobacco plants (see, e.g., page 5 of the draft Al-Ahmad et al article, top paragraph). Thus, Al-Ahmad et al do not provide enabling support for the claimed invention.

Applicant urges that the art rejections are improper, given the failure of the prior art to teach a "commercially desirable" trait. The Examiner maintains that antibiotic resistance is commercially desirable for identifying transformation events also including other agronomic transgenes. Furthermore, "commercially desirable" is defined in claim 23 as encompassing "herbicide resistance" and "genetically modified plant products". The Examiner maintains that the production of the neomycin phosphotransferase protein in transformed plants constitutes a "genetically modified plant product". Furthermore, antibiotics may be considered herbicides due to their toxicity to green plants including weeds. Finally, COLD SPRING HARBOR teaches the herbicide resistance BAR gene as well as the kanamycin resistance gene.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1638

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August 10, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read 'David T. Fox', followed by a large, stylized number '4'.